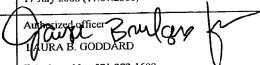


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 19025 024		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US04/38496	International filing date (day/month/year) 17 November 2004 (17.11.2004)	Priority date (day/month/year) 17 November 2003 (17.11.2003)	
International Patent Classification (IPC) or national classification and IPC IPC: C12Q 1/68(2006.01);C07H 21/00(2006.01);C07K 14/00(2006.01) USPC: 435/6;536/23.1;530/350			
Applicant PTC THERAPEUTICS, INC.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u> </u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 17 June 2005 (17.06.2005)		Date of completion of this report 17 July 2008 (17.07.2008)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201		Authorized officer  LAURA B. GODDARD Telephone No. 571-272-1600	

Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/38496

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
the description:
pages 1-63 _____ as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☒ the claims:
pages 64-68 _____, as originally filed
pages NONE _____, as amended (together with any statement) under Article 19
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☒ the drawings
pages 1-8 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
pages 1-12 _____, as originally filed
pages NONE _____, filed with the demand
pages NONE _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
☐ the claims, Nos. NONE
☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).
** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US04/38496**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-44 and 47-52</u>	YES
	Claims <u>45, 46, 53, 54</u>	NO
Inventive Step (IS)	Claims <u>1-44 and 47-52</u>	YES
	Claims <u>45, 46, 53, 54</u>	NO
Industrial Applicability (IA)	Claims <u>1-54</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 45 and 46 lack novelty under PCT Article 33(2) as being anticipated by US Patent 5,518,885, Raziuddin et al, issued May 21, 1996.

Raziuddin et al teach a nucleic acid SEQ ID NO:9 that comprises a fragment (nucleotides 4383-4455) that is 100% identical to SEQ ID NO:1 of the instant application. Given the nucleotide sequence taught by Raziuddin et al comprises SEQ ID NO:1 and is the same sequence as instantly claimed, it would modulate expression of a gene as recited in claim 46.

Claims 45 and 46 lack novelty under PCT Article 33(2) as being anticipated by WO 95/28485, Raziuddin et al, published October 26, 1995.

Raziuddin et al teach a nucleic acid SEQ ID NO:9 (p. 52-54) that comprises a fragment (nucleotides 4383-4455) that is 100% identical to SEQ ID NO:1 of the instant application. Given the nucleotide sequence taught by Raziuddin et al comprises SEQ ID NO:1 and is the same sequence as instantly claimed, it would modulate expression of a gene as recited in claim 46.

Claims 53 and 54 lack novelty under PCT Article 33(2) as being anticipated by Asano et al, Journal of Biological Chemistry, 1997, Vol. 272, p. 23477-23480.

Asano et al teach a protein with a molecular weight of approximately 48 kDa, which is the only required structure of the protein recited in claim 53. It is noted that sections (b)-(d) of claim 53 do not require a function of the protein. Given the protein taught by Asano et al is a 48 kDa protein as required by the claims, its expression would be regulated by a kinase.

Claims 1-44 and 47-52 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed methods as recited in claims 1-27, the cell line recited in claims 28-31, the hybrid recited in claims 32-44, and the nucleic acid of claim 47-48, and the methods of claims 49-52.

Claims 1-54 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

US 5,518,885 A (RAZIUDDIN et al) 21 May 1996, see SEQ ID NO:9.

WO 95/28485 (RAZIUDDIN et al) 26 October 1995, see SEQ ID NO:9.

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
DAVID R. MARSH
ARNOLD & PORTER LLP
555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-206

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year)

31 JUL 2008

Applicant's or agent's file reference

19025.024

IMPORTANT NOTIFICATION

International application No.

PCT/US04/38496

International filing date (day/month/year)

17 November 2004 (17.11.2004)

Priority date (day/month/year)

17 November 2003 (17.11.2003)

Applicant

PTC THERAPEUTICS, INC.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/US
Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Form PCT/IPEA/416 (January 2004)

Authorized officer

LAURA B. GODDARD

Telephone No. (571) 272-1600



PATENT COOPERATION TREATY

LPM

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
DAVID R. MARSH
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555 TWELFTH STREET, N.W.
WASHINGTON, DC 20004-206

PCT

NOTIFICATION OF TRANSMITTAL OF
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REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year)

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19025 024

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

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PCT/US04/38496

17 November 2004 (17.11.2004)

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Form PCT/IPEA/416 (January 2004)

